PATENT
Docket No. 40646
Client Reference 2000600

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Tami M. Procopio

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

David S. BURT et al.

Serial No.: 09/788, 280

Filing Date: February 15, 2001

For: PROTEOSOME INFLUENZA VACCINE

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

AMENDMENT

Prior to examination of the above-referenced application, please amend the specification as follows:

sd-43981

In the Specification:

Please amend the paragraph beginning on Page 7, line 15 as follows:

Figures 5A-5D are graphic representations of responses in serum and nasal mucosa to trivalent split influenza vaccines.

Please amend the paragraph beginning on Page 30, Line 9 as follows:

Trivalent proteosome influenza vaccines were prepared using the procedure outlined in Example 3 using detergent split antigens from the A/Beijing/26/95 (H1N1), A/Sydney/05/97 (H3N2) and B/Yamanashi/166/98 sub-types of influenza virus. As shown in Fig. 5A-D for proteosome-flu vaccines made with each strain individually and combining them as a trivalent, strain specific serum IgG (Fig. 5A and C) and nasal IgA (Fig. 5B and D) responses are enhanced compared to their non-proteosome complexed controls. The immunoglobulin titers induced by the monovalent and trivalent proteosome-flu vaccines are not significantly different. Thus vaccines comprising multivalent influenza antigens induce serum and mucosal immune responses against each component, equivalent to that induced by the individual univalent vaccines.

REMARKS

Applicant received a Notice to File Missing Parts mailed 3/20/01, wherein it indicated that Figures 5E-F were referenced in the specification, but not supplied with the initial application. Applicant has therefore deleted all references to Figures 5E-F and has attached hereto a formal drawing for Figures 5A-D. Also attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 40646-20006.00. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: June 13, 2001

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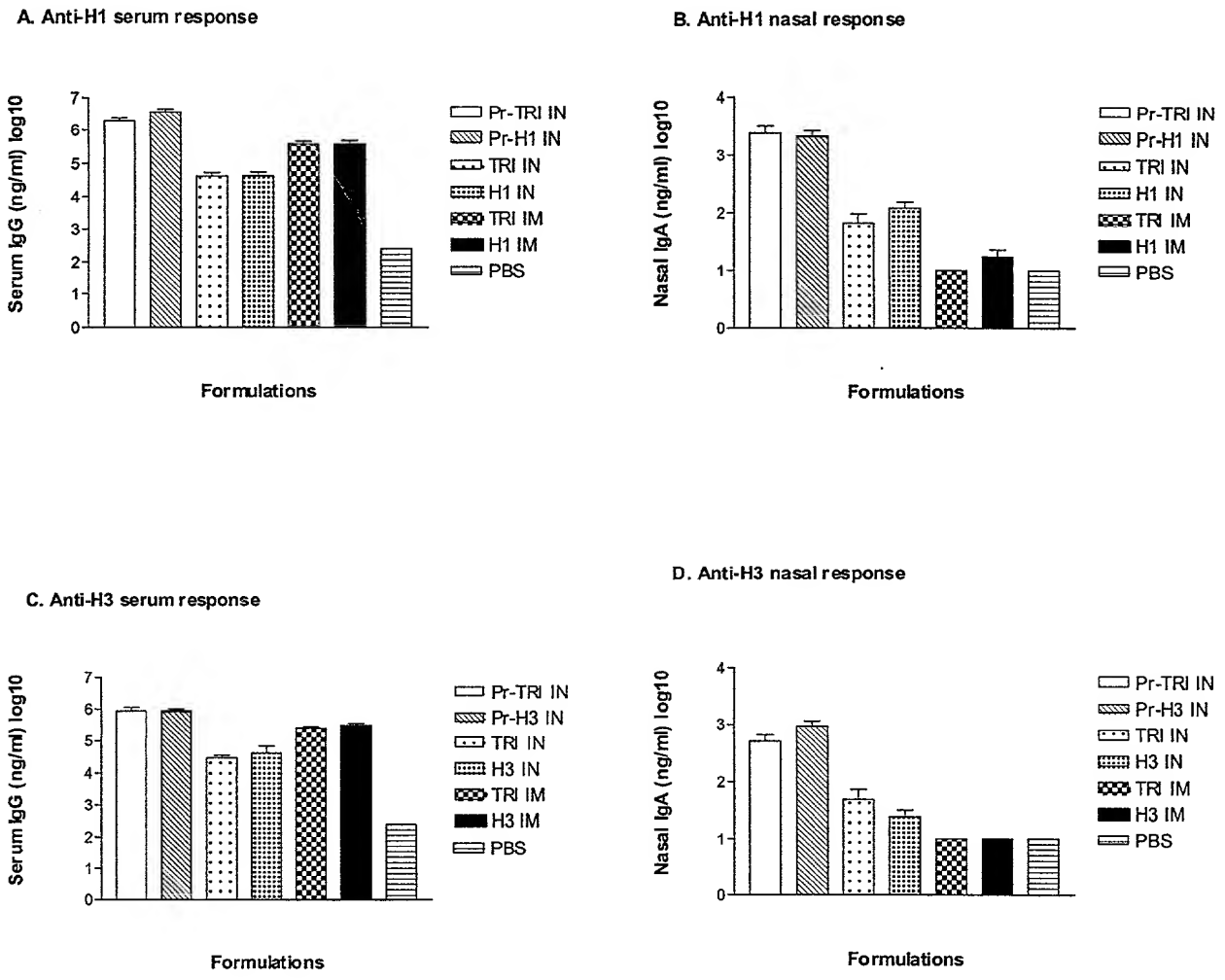
VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Figures 5A-5[F] D are graphic representations of responses in serum and nasal mucosa to trivalent split influenza vaccines.

Trivalent proteosome influenza vaccines were prepared using the procedure outlined in Example 3 using detergent split antigens from the A/Beijing/26/95 (H1N1), A/Sydney/05/97 (H3N2) and B/Yamanashi/166/98 sub-types of influenza virus. As shown in Fig. 5A-[F] D for proteosome-flu vaccines made with each strain individually and combining them as a trivalent, strain specific serum IgG (Fig. 5A[,] and C [and E]) and nasal IgA (Fig. 5B[,] D [and E]) responses are enhanced compared to their non-proteosome complexed controls. The immunoglobulin titers induced by the monovalent and trivalent proteosome-flu vaccines are not significantly different. Thus vaccines comprising multivalent influenza antigens induce serum and mucosal immune responses against each component, equivalent to that induced by the individual univalent vaccines.

Fig. 5


A. Anti-H1 serum response
Serum IgG (ng/ml) log10
Formulations
Pr-TRI IN
Pr-H1 IN
TRI IN
H1 IN
TRI IM
H1 IM
PBS
B. Anti-H1 nasal response
Nasal IgA (ng/ml) log10
Formulations
C. Anti-H3 serum response
Serum IgG (ng/ml) log10
Formulations
Pr-H3 IN
H3 IN
H3 IM
D. Anti-H3 nasal response
Nasal IgA (ng/ml) log10
Formulations